DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-532/S-008

EnviroDerm Pharmaceuticals, Inc.
Attention: David W. Schropfer
President
1600 West Hill Street
Louisville, KY 40210

Dear Mr. Schropfer:

Please refer to your supplemental new drug application dated June 9, 1999, received June 10, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ivy Block Lotion (Bentoquatam 5%).

We acknowledge receipt of your submissions dated June 12, 2000 and May 2, 2001.

This supplemental new drug application provides for a new label for the approved market packages for Ivy Block Lotion and revises the drug claim from "Helps Protect" to "Helps Prevent".

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (immediate container labels submitted June 12, 2000, with modifications agreed upon in your May 2, 2001 correspondence) and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit according to the guidance for industry titled (*Providing Regulatory Submissions in Electronic Format – NDA*) (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-532/S-008." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane

Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Walter Ellenberg, Regulatory Project Manager, at 301-827-2222.

Sincerely,

{See appended electronic signature page}

Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research